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MAR - 9 2001

SUMMARY OF SAFETY AND EFFECTIVENESS
Nidek Incorporated OPD-Scan™ Device

SUBMITTER INFORMATION

A.	Company Name:	Nidek Incorporated
B.	Company Address:	47651 Westinghouse Drive. Fremont, CA 94539-7474
C.	Company Phone: Company Fax:	(510) 353-7719 (510) 226-5750
D.	Contact Person:	Mr. Hiroshi Okada Vice President & General Manager Nidek Incorporated
E.	Date Summary Prepared:	October 11, 2000

DEVICE IDENTIFICATION

A.	Generic Device Name:	Keratoscope and Ophthalmic Refractometer
B.	Trade/Proprietary Name:	OPD-Scan™ Device
C.	Classification:	Class I
D.	Product Code:	HLQ and HKO

SUBSTANTIAL EQUIVALENCE

The Nidek Incorporated OPD-Scan™ device is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Wavescan™ Wavefront System	VISX, Inc.	K000327	5/2/2000
Orbscan™ Keratometer	ORBTEK, Inc.	K940647	7/6/1994

DEVICE DESCRIPTION

The OPD-Scan™ device combines corneal topography (video keratometer and analysis system) with refractive power mapping functions into a single instrument for analysis of both low and high order optical aberrations. The power mapping function is similar to wavefront technology in that higher order optical aberrations throughout the eye's entire optical system are measured. The OPD-Scan™ instrument also performs as a spatial autorefractor, measuring the Sphere, Cylinder, and Axis values of the central cornea. Combining these functions (corneal topography, refractive power mapping and autorefractometry) in a single instrument minimizes errors induced by patient misalignment that can occur when using separate instruments.

INTENDED USE

The OPD-Scan™ device is intended for use in:

- Mapping the display of the refractive power distribution of the eye, by measurement and analysis of the spherical power, cylindrical power, and cylinder axis.

- The measurement and analysis of corneal curvature (corneal refractive power), cylindrical power, and cylinder axis of the cornea. The device also maps the display of the corneal shape.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the OPD-Scan™ Device and the predicate device has been performed. The results of this comparison demonstrate that the OPD-Scan™ Device is equivalent to the marketed predicate devices

PERFORMANCE DATA

The performance data indicate that the OPD-Scan™ device meets all specified requirements, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 - 2001

Nidek Co., Ltd.
C/O Ms. Carol L. Patterson, President
Patterson Consulting Group Inc.
21911 Erie Lane
Lake Forest, CA 92630

Re: K003299
Trade Name: OPD-Scan Models ARK-10000 and ARK-9000
Regulatory Class: I
Product Code: HLQ and HKO
Regulation 21 CFR Parts 886.1760 and 1350
Dated: January 31, 2001
Received: February 1, 2001

Dear Ms. Patterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of using the data from the OPD-Scan (Model Numbers ARK-10000 and ARK-9000) have not been established for determining treatments involving higher order aberrations of the eye such as coma and spherical aberrations.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions.

Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K003299 (To Be Assigned By FDA)

Device Trade Name: OPD-Scan™, Model Numbers ARK-10000 & ARK-9000

Indications For Use: The OPD-Scan™ is a diagnostic instrument that is indicated for use:

- In the automated measurement and analysis of refractive errors of the eye including hyperopia and myopia from –20.0 to +22.0 diopters spherical, and astigmatism from 0.0 to ± 12.0 diopters cylinder.
- In the measurement and evaluation of the corneal curvature of the eye.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dennis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003299

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)